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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/597,608 06/20/00 NGAI

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RICHARD ARON OSMAN
SCIENCE AND TECHNOLOGY LAW GROUP
75 DENISE DRIVE
HILLSBOROUGH CA 94010

EXAMINER

TAYLOR, J
ART UNIT PAPER NUMBER

1655
DATE MAILED:

02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/597,608	NGAI ET AL.	
	Examiner	Art Unit	
	Janell Taylor Cleveland	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-18 is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The following Office Action is in response to the amendment received Dec. 28, 2000.

Any rejection not reiterated is withdrawn. Because this Office Action contains a **NEW GROUNDS OF REJECTION**, this Action is considered **NON-FINAL**.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Catalog, 1995, page109.

The claim is drawn to a kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1, and a premeasured portion of a reagent selected from the group consisting of: oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Because no patentable weight is given to instructions describing a method (the instructions are considered to be merely printed matter), the claim is anticipated by Stratagene. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label

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on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers and buffer, among other things. Therefore, all of the limitations of the instant claim are anticipated by Stratagene.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene in view of Serafini et al. in view of Hampson et al. (USPN 5,591,575).

Claim 20 depends from claim 19, and comprises premeasured portions of oligo dT T7 biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, RNase H, DNA pol I, buffers, and nucleotides.

Stratagene teaches a kit for amplifying an RNA population, which contains reverse transcriptase, nucleotides, RNase, primers and buffer (page 161).

Stratagene does not teach the use of biotinylated primers and streptavidin beads, or polyadenyl transferase, or DNA pol I.

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Serafini et al. teach polyadenyltransferase and DNA polymerase (Cols. 3-4).

Hampson et al. teach biotinylated primer and streptavidin beads (claim 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the kit of Stratagene by adding biotinylated primers and streptavidin beads, as well as polyadenyl transferase and DNA pol I. This is because it was well known in the art at the time of the invention that biotinylated primers and streptavidin beads were very effective in capturing and identifying an amplified nucleic acid. It would also have been obvious to add polyadenyl transferase and DNA pol I because it was well known in the art at the time of the invention that polyadenyl transferase was useful for adding poly(A) sequence, and DNA polymerase was necessary for amplification. All of these items would have been useful in a kit because they all had well known uses in the art.

Summary

Claim 19 is rejected under 35 USC 102(b). Claim 20 is rejected under 35 USC 103(a). Claims 1-18 are free of the prior art and are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.


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Any inquiries of a general nature relating to this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

February 20, 2001


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
2/21/01